K101063 (1/2)

BIOMET
SPORTS MEDICINE

JUN 2 8 2010

510(k) Summary

Preparation Date: June 17, 2010

Applicant/Sponsor: Biomet Sports Medicine

Contact Person: Robert Friddle
Regulatory Affairs Specialist

Proprietary Name: Sleeve with ZipLoop™ Fixation Devices

Common Name: Soft tissue fixation device

Classification Name:
- MBI (888.3040): Fastener, fixation, nondegradable, soft tissue
- JDR (888.3030): Staple, Fixation, Bone

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

K071704	Sleeve and Button Soft Tissue Devices
K973015	Multitak SS Suture System™
K053344	BioRaptor™ Suture Anchors

Device Description:
The Sleeve with ZipLoop™ Fixation Devices are a three component assembly consisting of two sleeves and a ZipLoop™ construct. The ZipLoop™ construct is an adjustable loop created with a single piece of fiber material. When the ZipLoop™ is pulled tight, the sleeve locks against the bone fixating the soft tissue. The Sleeve with ZipLoop™ Fixation Devices provide the surgeon with a means to aid in the management of soft tissue to bone reattachment procedures.

Intended Use/Indications for Use:
The Sleeve with ZipLoop™ Fixation Devices are intended for fixation for the following indications:

Shoulder
Bankart lesion repair, SLAP lesion repair, Acromio-clavicular repair, Capsular shift/capsulolabral reconstruction, Deltoid repair, Rotator cuff tear repair, Biceps tenodesis

Foot and Ankle
Medial/lateral repair and reconstruction, Mid- and forefoot repair, Hallux valgus reconstruction, Metatarsal ligament/tendon repair or reconstruction, Achilles tendon repair

Elbow
Ulnar or radial collateral ligament reconstruction, Lateral epicondylitis repair, Biceps tendon reattachment

Mailing Address:
P.O. Box 587
Warsaw, IN 46581-0587
Toll Free: 800.348.9500
Office: 574.267.6639
Main Fax: 574.267.8137
www.biomet.com

Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

Knee
Extra-capsular repair: MCL, LCL, and posterior oblique ligament, Iliotibial band tenodesis, Patellar tendon repair, VMO advancement, Joint capsule closure

Hand and Wrist
Collateral ligament repair, Scapholunate reconstruction, Tendon transfers in phalanx, Volar plate reconstruction

Hip
Acetabular labral repair

Summary of Technologies: The technological characteristics (materials, design, sizing and indications) of the Sleeve with ZipLoop™ Fixation Devices are similar or identical to the predicate devices or other previously cleared devices.

Non-Clinical Testing: Non-clinical laboratory testing was performed to verify the fixation strength of the Sleeve with ZipLoop™ Fixation Devices in pullout tests as compared to the predicate devices for specific indications for use. The test results indicate that the Sleeve with ZipLoop™ Fixation Devices provide equivalent pullout strength to the predicate devices and would be functional within their intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Biomet Sports Medicine
% Mr. Robert Friddle
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

JUN 2 3 2010

Re: K101063
Trade/Device Name: Sleeve with ZipLoop™ Fixation Devices
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI
Dated: April 15, 2010
Received: April 16, 2010

Dear Mr. Friddle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101063

Device Name: Sleeve with ZipLoop™ Fixation Devices

Indications for Use:

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Hip
Acetabular labral repair

Prescription Use X AND/OR Over-The-Counter Use NO
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101063